

Claim Summary:

1. (currently amended) A composition of matter comprising a spray dried solid dispersion, which dispersion
is homogeneous;
comprises a sparingly water-soluble drug having a dose to aqueous solubility ratio greater than 100 mL and hydroxypropylmethylcellulose acetate succinate (HPMCAS), said drug being molecularly dispersed and amorphous in said dispersion;
comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;
provides a maximum concentration of said drug in a use environment that is higher by a factor of at least 1.5 relative to a control composition comprising an equivalent quantity of undispersed drug; and
has a drug:polymer weight ratio between 1:0.5 and 1:100 1:0.4 and 1:20; and
satisfies either of the following tests:

- (a) providing a maximum concentration of said drug in MFD (model fasted duodenal fluid) that is higher by a factor of at least 1.5 relative to a control composition;
wherein MFD is water which is 82 mM in NaCl, 20 mM in Na₂HPO₄, 47 mM in KH₂PO₄, 14.7 mM in sodium taurocholate and 2.8 mM in 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine to yield a solution pH of about 6.5 and osmotic pressure of about 290 mOsm/kg, or
- (b) effecting, *in vivo*, a maximal observed blood drug concentration (C_{max}), that is higher by a factor of at least 1.25 relative to a control composition;

wherein the control composition is identical to the test composition except that it comprises pure drug in its equilibrium form and does not comprise HPMCAS, or the HPMCAS is replaced by an equal amount of inert, non-adsorbing solid diluent and the test composition and control composition are tested under like or standardized conditions.

2. (canceled)

3. (canceled)

4. (original) A composition as defined in claim 1, wherein said drug is amorphous when undispersed.

5-14. (canceled)

15. (currently amended) A composition of matter comprising a spray dried solid dispersion, which dispersion

~~is homogeneous;~~

comprises a sparingly water-soluble drug ~~having a dose to aqueous solubility ratio greater than 100 mL~~ and HPMCAS, said drug being molecularly dispersed and amorphous in said dispersion;

~~comprises spray dried particles that are solidified in less than 5 seconds and that have a residual solvent content less than 10 wt%;~~

effects, *in vivo*, an area under a curve (AUC) plotting the serum or plasma concentration of drug along the ordinate against time on the abscissa that is higher by a factor of at least 1.25 relative to a control composition comprising an equivalent quantity of undispersed drug; and

has a drug:polymer weight ratio between ~~4:0.5 and 1:100~~ 1:0.4 and 1:20.

16. (canceled)

17. (original) A composition as defined in claim 15, wherein said drug is amorphous when undispersed.

18. (canceled)

19. (canceled)

20. (canceled)

21. (canceled)

22. (original) A composition as defined in claim 1, wherein the concentration of drug in MFD falls to no less than 25% of the maximum supersaturated

concentration during the 15 minutes following the time at which the maximum supersaturated concentration is reached.

23. (original) A composition as defined in claim 1, wherein said dispersion is in the form of particles less than 100 μm in diameter.

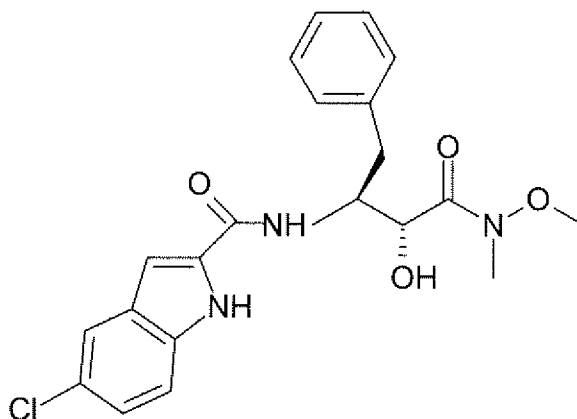
24-25. (canceled)

26. (original) A composition as defined in claim 15, wherein said dispersion is in the form of particles less than 100 μm in diameter.

27. (canceled)

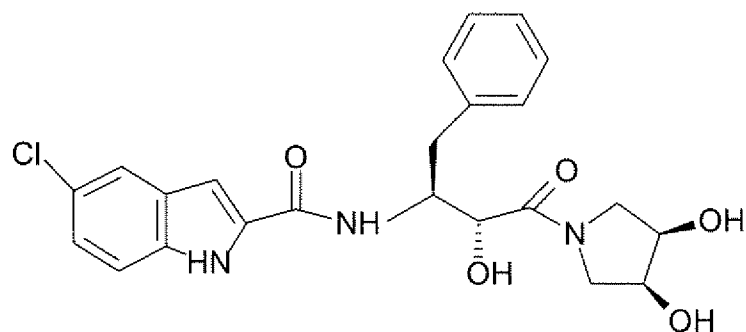
28. (currently amended) A composition as defined in claims 1 and 15 ~~4, 7, 11, 15, 39, 43, 45, or 47~~ wherein said drug is a glycogen phosphorylase inhibitor.

29. (currently amended) A composition as defined in claims 1 and 15 ~~4, 7, 11, 15, 39, 43, 45, or 47~~ wherein said drug is



or a pharmaceutically acceptable salt thereof.

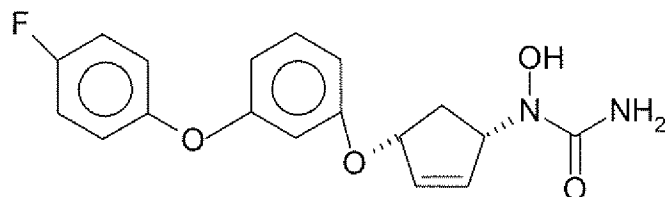
30. (currently amended) A composition as defined in claims 1 and 15 ~~4, 7, 11, 15, 39, 43, 45, or 47~~ wherein said drug is



or a pharmaceutically acceptable salt thereof.

31. (currently amended) A composition as defined in claims 1 and 15 ~~1, 7, 11, 15, 39, 43, 45, or 47~~ wherein said drug is a 5-lipoxygenase inhibitor.

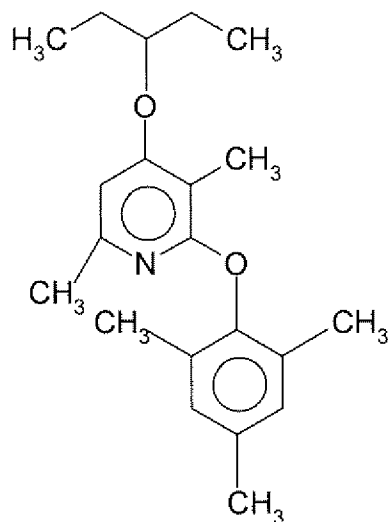
32. (currently amended) A composition as defined in claims 1 and 15 ~~1, 7, 11, 15, 39, 43, 45, or 47~~ wherein said drug is



or a pharmaceutically acceptable salt thereof.

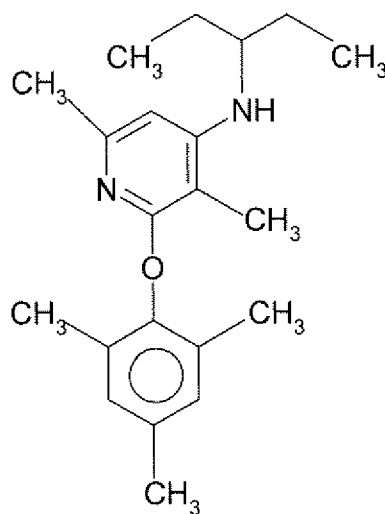
33. (currently amended) A composition as defined in claims 1 and 15 ~~1, 7, 11, 15, 39, 43, 45, or 47~~, wherein said drug is a corticotrophic releasing hormone (CRH) inhibitor.

34. (currently amended) A composition as defined in claims 1 and 15 ~~1, 7, 11, 15, 39, 43, 45, or 47~~, wherein said drug is



or a pharmaceutically acceptable salt thereof.

35. (currently amended) A composition as defined in claims 1 and 15 4, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is



or a pharmaceutically acceptable salt thereof.

36. (currently amended) A composition as defined in claims 1 and 15 4, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is an antipsychotic.

37. (currently amended) A composition as defined in claims 1 and 15 4, 7, 11, 15, 39, 43, 45, or 47, wherein said drug is ziprasidone.

38. (currently amended) A composition as defined in claims 1 and 15 ~~1, 7, 11, 15, 39, 43, 45, or 47~~, wherein said drug is selected from griseofulvin, nifedipine, and phenytoin.

39-48 (canceled)

49. (currently amended) A composition as defined in claims 1 and 15, ~~4, 7, 11, 15, 39, 43, 45 or 47~~ wherein said particles wherein said dispersion comprises spray dried particles that are solidified in less than 2 seconds.

50. (currently amended) A composition as defined in claims 1 and 15 ~~4, 7, 11, 15, 39, 43, 45 or 47~~ wherein said particles have a residual solvent content less than 2 wt%.

51. (currently amended) A composition as defined in claims 1 and 15 ~~4, 7, 11, 15, 39, 43, 45 or 47~~ wherein said particles are spray-dried from a solution in which the concentration of drug in the solvent is less than 20g/100g and in which the total solids content is less than 25 weight %.

52. (canceled)

53. (new) A composition as defined in claims 1 and 15, wherein said drug has a dose to aqueous solubility ratio greater than 100.

54. (new) A composition as defined in claims 1 and 15, wherein said drug is crystalline when undispersed.

55. (new) A composition as defined in claims 1 and 15, having a drug:polymer weight ratio between 1:0.5 and 1:20.

56. (new) A composition as defined in claims 1 and 15, having a drug:polymer weight ratio between 1:1 and 1:20.